

RETAILER REQUIREMENTS: NEW WARNING STATEMENT REQUIREMENTS FOR CERTAIN TOBACCO PRODUCTS

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CENTER FOR TOBACCO PRODUCTS

- Notice: The material presented in this webinar does not apply to cigars and pipe tobacco, nor is it intended to communicate regulatory requirements for these products. For up to date information about the regulatory requirements for cigars and pipe tobacco, please visit the FDA, Center for Tobacco Products website.

ADDICTIVENESS WARNING STATEMENT



- For cigarette tobacco, roll-your own tobacco, and covered tobacco products (except for their parts and components that do not contain nicotine), the addictiveness warning statement must appear on product packages and advertisements for these products.
- If the product does not contain nicotine and is made or derived from tobacco, the tobacco product manufacturer may display the alternative warning statement, instead of the nicotine addictiveness warning statement, upon submission of a self-certification statement to FDA.
- The alternative warning statement, under 21 CFR § 1143.3(c), for applicable product packages and advertisements reads:

This product is made from tobacco.

ADDICTIVENESS WARNING STATEMENT



WARNING: This product contains nicotine. Nicotine is an addictive chemical.

- Size and placement requirements apply. Please refer to the guidance:

Small Entity Compliance Guide: FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements

ADDICTIVENESS WARNING STATEMENT



- Manufacturers cannot manufacture products for sale or distribution within the United States with non-compliant packages beginning August 10, 2018, and cannot distribute such products within the United States beginning September 11, 2018, irrespective of the date of manufacture.
- Distributors and retailers may continue to sell and distribute after August 10, 2018 covered tobacco products, cigarette tobacco, and RYO tobacco products with non-compliant packages only if the products were manufactured before August 10, 2018.

RETAILER SAFE HARBOR FOR PACKAGING



A retailer will not be in violation of the warning statement requirements for packaging that:

- Contains a health warning;
- Is supplied to the retailer by a tobacco product manufacturer, importer, or distributor who has the required state, local, or Alcohol and Tobacco Tax and Trade Bureau (TTB)-issued license or permit, if applicable; and
- Is not altered by the retailer in a material way. (for example, putting a sticker over the health warning)

- **Small Entity Compliance Guide: FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements**

THE END

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